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BLOOD PRODUCTS ADVISORY COMMITTEE
69th Meeting - June 14-15, 2001
Gaithersburg Hilton, 620 Perry Parkway
Gaithersburg, MD 20877

Thursday, June 14, 2001

8:30 a.m. Statement of Conflict of Interest

8:35 a.m. Welcome and Opening Remarks

8:40 a.m. Committee Updates

- Meeting Summary on Blood Safety and Availability PHS Advisory Committee, April 19-20, 2001 - Stephen Nightingale, M.D.
- Current Thinking: Clinical Trial Design and Performance Standards for Approval of Rapid HIV Tests - Elliot Cowan, Ph.D.
- Proposed FDA Scientific Workshops - Linda A. Smallwood, Ph.D.

9:00 a.m. Open Committee Discussion

I. Re-entry for Donors Deferred Because of HIV or HCV
NAT or Serological Test Results

- A. Introduction and Background - Paul A. Mied, Ph.D.
Deputy Director, Division of Emerging and
Transfusion Transmitted Diseases, OBRR
- B. Presentation - Michael Busch, M.D., Ph.D., Blood
Centers of the Pacific, CA
- C. Presentation - Susan Stramer, Ph.D., American Red
Cross
- D. Presentation - Susan Galel, M.D., Stanford
University

10:15 a.m. OPEN PUBLIC HEARING

10:45 a.m. BREAK

11:00 a.m. Open Committee Discussion

- E. Questions for the Committee
- F. Committee Discussion and Recommendations

12:30 NOON LUNCH

1:30 p.m. Open Committee Discussion

II. CLIA Criteria for In Vitro Diagnostic Tests:
Applicability of Waivers to HIV Rapid Tests

- A. Introduction and Background - Elliot Cowan, Ph.D.
DETTD, OBRR, CBER
- B. Historical Overview of CLIA Waivers - Thomas
Hearn, Ph.D., CDC
- C. Overview of FDA Draft Guidance for CLIA Criteria
for Waiver - Joseph Hackett, Ph.D., DCLD, ODE, CDRH
- D. Public Health Strategic Goals for HIV Testing -
Ida Onorato, M.D., CDC
- E. Requirements for Moderate Complexity Tests and
HCFA Experience with CLIA Waived Tests in the
Laboratory - Judith Yost, HCFA
- F. FDA Perspectives on CLIA Waiver of Rapid HIV Tests
and Questions for the Committee - Elliot Cowan,
Ph.D., DETTD, OBRR, CBER

2:30 p.m. OPEN PUBLIC HEARING

3:00 p.m. *Open Committee Discussion*

G. Committee Discussion and Recommendations

4:00 p.m. BREAK

4:15 p.m. *Open Committee Discussion*

III. Revision of the Uniform Donor History Questionnaire
- Informational Presentation

- A. Overview and Introduction - Alan Williams, Ph.D.
Director, Division of Blood Applications
- B. Update on AABB Task Force Programs - Joy Fridey,
M.D., AABB
- C. Presentation of Proposed Modifications to Uniform
Donor History Questionnaire - Susan Orton, M.D.
ARC

4:45 p.m. OPEN PUBLIC HEARING

5:00 P.M. *Open Committee Discussion*

D. Committee Discussion and Recommendations

5:30 p.m. RECESS (until 8:30 a.m., Friday, June 15, 2001)

Friday, June 15, 2001

8:30 a.m. Committee Updates

- DHHS TSE/BSE Action Plan - Steven Nightingale, M.D.
- OBRR TSE/BSE Action Plan - Mary Elizabeth Jacobs, Ph.D.
- Update on Transmissible Spongiform Encephalopathies Advisory Committee Meeting to be held on June 28-29, 2001 - TBD

9:00 a.m. *Open Committee Discussion*

IV. Transfusion-Related Acute Lung Injury -
Informational Presentation

- A. Introduction and Background - Leslie Holness, M.D., Medical Officer, Division of Blood Applications
- B. Presentation - Mark Popovsky, M.D., Haemonetics Corp.
- C. Presentation - Patricia Kopko, M.D., Sacramento Blood Center
- D. Presentation - Lynn K. Boshkov, M.D., Oregon Health Sciences University
- E. Presentation - John Finlayson, Ph.D., Associate Director for Science, OBRR

10:15 a.m. OPEN PUBLIC HEARING

10:45 a.m. BREAK

11:00 a.m. *Open Committee Discussion*

F. Committee Discussion and Recommendations

11:45 a.m. LUNCH

12:45 p.m. *Open Committee Discussion*

V. Studies on Leukoreduction Filtration Failures

- A. Introduction and Background - Betsy Poindexter, Biologist, Lab. of Cellular Hematology, DH
- B. Presentation - Constance Noguchi, Ph.D., NIH
- C. Presentaton - Thomas Walker, M.D., Canadian Blood Services

D. Presentation - Rebecca Haley, M.D., American Red Cross

E. Presentation - Cheri Jennings, Gulf Coast Blood Center

F. Presentation - Glenda Ford, Oklahoma Blood Institute

1:45 p.m. OPEN PUBLIC HEARING

2:15 p.m. *Open Committee Discussion*

G. Committee Discussion and Recommendations

2:45 p.m. VI. Report of the Intramural Site Visit of the Laboratory of Plasma Derivatives, Division of Hematology, OBRR

A. Introduction and Overview

- Neil Goldman, Ph.D., Associate Director for Research, CBER

- John Finlayson, Ph.D., Associate Director for Science, OBRR

- Basil Golding, M.D., Chief, Lab. of Plasma Derivatives, DH

3:15 p.m. *Closed Committee Deliberations*

B. Committee Discussion and Recommendations

3:45 p.m. Adjournment